

Attorney Docket No.: CJL-0002  
Inventors: Odidi and Odidi  
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This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claim 1 (currently amended): A method of preparing a deformable syntactic foam for the delivery of a compound or chemical, the method comprising:

- a) mixing together one or more homopolymer resins, one or more binders, and one or more stabilizers to form a blended mixture having a LOD of from about 1% to about 10%; and
- b) ~~reacting~~ mixing said blended mixture with one or more organic solvents under conditions of high shear at temperatures of from about 10°C to about 25°C until a foam composition is formed wherein said foam composition is deformable ~~to the touch~~.

Claim 2 (original): The method according to claim 1 wherein said mixture in step (a) further comprises a particulate substance.

Claim 3 (original): The method according to claim 2 wherein said particulate substance is substantially spherical.

Claim 4 (original): The method according to claim 3 wherein said particulate substance is a plurality of microspheres.

Claim 5 (currently amended): The method according to claim 4 wherein during the ~~reaction~~ mixing in step a) the LOD is checked

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intermittently until the LOD of the reacted mixture is from about 2 percent to about 25 percent.

Claim 6 (original): The method according to claim 5 comprising a further step of separating said syntactic foam into particles.

Claim 7 (original): The method according to claim 6 wherein said syntactic foam is lyophilized or freeze dried before separating said syntactic foam into particles.

Claim 8 (original): The method according to claim 7 wherein said further step of separating comprises milling the foam.

Claim 9 (original): The method according to claim 8 wherein said step of separating further comprises a drying step at from about 25°C to about 60°C.

Claim 10 (original): The method according to claim 9 wherein the approximate diameter of said particles is about 1000µm.

Claim 11 (original): The method according to claim 9 wherein the approximate diameter of said particles is less than about 1000µm.

Claim 12 (original): The method according to claim 7 wherein said step of separating is preceded by a step of treating said syntactic foam to make it rigid.

Claim 13 (original): The method according to claim 12

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wherein said step of treating said syntactic foam to make rigid comprises contacting said syntactic foam with a cryogenic fluid.

Claim 14 (original): The method according to claim 13 wherein said cryogenic fluid is selected from the group consisting of liquid nitrogen and liquid carbon dioxide.

Claim 15 (original): The method according to claim 14, wherein the approximate diameter of said particles is about 1000 $\mu$ m.

Claim 16 (original): The method according to claim 14 wherein the approximate diameter of said particles is less than about 1000 $\mu$ m.

Claim 17 (original): The method according to claim 6 wherein the particles are subsequently molded into a shaped composite.

Claim 18 (original): The method according to claim 17 wherein the shape of the shaped composite is selected from the group of shapes consisting of round, triangular, rectangular, polygonal, cylindrical, oval, oblong, capsule, tablet and caplet.

Claim 19 (original): The method according to claim 18 wherein said stabilizer is silicic anhydride.

Claim 20 (original): The method according to claim 19 wherein said organic solvent is 2-propanol.

Claim 21 (original): The method according to claim 20

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wherein the homopolymer resin is a carboxyvinyl polymer.

Claim 22 (original): The method according to claim 21 wherein the microspheres are selected from the group consisting of silica, sucrose, glucose, lactose, dextrose, sorbitol, mannitol, xylitol, dextrans, poly(lactic acid), poly(glycolic acid), poly(glycolic acid-co-lactic acid), poly( $\epsilon$ -caprolactone), poly(malic acid), cellulose, microcrystalline cellulose, metal, glass and small beads.

Claim 23 (original): The method according to claim 22 wherein the microspheres are cellulose microspheres.

Claim 24 (original): The method according to claim 23 wherein the blended mixture further comprises a binder.

Claim 25 (currently amended): The method according to claim 24 wherein the binder is selected from the group consisting of high molecular weight polysaccharide, xanthan gum, d- $\alpha$ -tocopherol polyethylene glycol 1000 succinate, starch NF, povidone, copolyvidone NF, polyvinyl alcohols, glyceryl behenate, ~~xanthan gum,~~ polyethelene glycols, polyethelene oxides, cellulose binders, hydroxypropyl Methylcellulose USP and hydroxyethyl Cellulose NF.

Claim 26 (original): The method according to claim 25 wherein the binder is a high molecular weight polysaccharide.

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Claim 27 (currently amended): The method according to ~~claim 26~~ claim 25 wherein the high molecular weight polysaccharide is Xanthan gum.

Claim 28 (currently amended): The method according to ~~claim 27~~ claim 25 wherein the ~~xanthan gum binder~~ is d- $\alpha$ -tocopherol polyethylene glycol 1000 succinate.

Claim 29 (currently amended): A method of manufacturing a pharmaceutical carrier, the method comprising the steps of:

a) mixing together:

- i) one or more pharmaceutically acceptable homopolymer resins;
- ii) one or more pharmaceutically acceptable binders;
- iii) pharmaceutically acceptable microspheres, and
- iv) one or more pharmaceutically acceptable stabilizers to form a blended mixture having an LOD of from about 1% to about 10%;

b) ~~reacting~~ mixing said blended mixture with one or more pharmaceutically acceptable organic solvents under conditions of high shear at temperatures of from about 10°C to about 25°C until a foam composition is formed wherein said foam composition is deformable ~~to the touch~~; and

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c) reducing the size of the deformable syntactic foam to permit reassembly into a shaped composite.

Claim 30 (original): The method according to claim 29 wherein said deformable syntactic foam is reduced in size by drying (LOD less than about 5%) and then milling.

Claim 31 (original): The method according to claim 30 wherein said stabilizer is silicic anhydride.

Claim 32 (original): The method according to claim 31 wherein said organic solvent is 2-propanol.

Claim 33 (original): The method according to claim 32 wherein the homopolymer resin is a carboxyvinyl polymer.

Claim 34 (original): The method according to claim 33 wherein the microspheres are selected from the group consisting of silica, sucrose, glucose, lactose, dextrose, sorbitol, mannitol, xylitol, dextrates, poly(lactic acid), poly(glycolic acid), poly(glycolic acid-co-lactic acid), poly( $\epsilon$ -caprolactone), poly(malic acid), cellulose, microcrystalline cellulose, metal, glass and small beads.

Claim 35 (original): The method according to claim 34 wherein the microspheres are cellulose microspheres.

Claim 36 (original): The method according to claim 35 wherein the blended mixture further comprises a binder.

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Claim 37 (currently amended): The method according to claim 36 wherein the binder is selected from the group consisting of high molecular weight polysaccharide, xanthan gum, d- $\alpha$ -tocopherol polyethylene glycol 1000 succinate, starch NF, povidone, copolyvidone NF, polyvinyl alcohols, glyceryl behenate, ~~xanthan gum~~, polyethelene glycols, polyethelene oxides, cellulose binders, hydroxypropyl Methylcellulose USP and hydroxyethyl Cellulose NF.

Claim 38 (original): The method according to claim 37 wherein the binder is a high molecular weight polysaccharide.

Claim 39 (currently amended): The method according to ~~claim 38~~ claim 37 wherein the ~~high molecular weight polysaccharide binder~~ is Xanthan gum.

Claim 40 (currently amended): The method according to ~~claim 39~~ claim 37 wherein the ~~xanthan gum binder~~ is d- $\alpha$ -tocopherol polyethylene glycol 1000 succinate.

Claim 41 (original): A pharmaceutical composition comprising a pharmaceutical and a pharmaceutical carrier wherein said pharmaceutical carrier is prepared in accordance with the method of claim 29.

Claim 42 (original): The composition according to claim 41 wherein the pharmaceutical is selected from the group consisting

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of human and veterinary medicines.

Claim 43 (original): The composition according to claim 42 wherein the pharmaceutical active is selected from the group of pharmaceuticals having one or more active ingredients selected from the group consisting of Acarbose, Acetaminophen/Codeine, Albuterol, Alendronate, Allopurinol, Alprazolam, Amitriptyline, Amlodipine, Amlodipine/Benazepril, Amoxicillin, Amoxicillin/Clavulanate, Amphetamine Mixed Salts, Aspirin, Atenolol, Atorvastatin, Azithromycin, Beclomethasone, Benazepril, Bisoprolol/HCTZ, Brimonidine, Carbidopa-Levodopa, Calcitonin, Carisoprodol, Carvedilol, Cefprozil, Cefuroxime, Celecoxib, Cephalexin, Cetirizine, Ciprofloxacin, Cisapride, Citalopram, Clarithromycin, Clonazepam, Clonidine, Clopidogrel, Clotrimazole/Betamethasone, Cyclobenzaprine, d-phenylalanine amino acid derivative, Diazepam, Misoprostol, Digoxin, Divalproex, Donepezil, Doxazosin, Enalapril, Erythromycin, Estradiol, Ethinyl Estradiol/Norethindrone, Famotidine, Felopidine, Fexofenadine, Fexofenadine/Pseudoephedrine, Fluoxetine, Fluticasone Propionate, Fluvastatin, Fluvoxamine, Fosinopril, Furosemide, Gemfibrozil, Glimepiride, Glyburide, Granisetron, Guaifenesin/Phenylpropanolamine, Hydrochlorothiazine, Hydrocodone w/APAP, Ibuprofen, Ipratropium,

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Ipratropium/Albuterol, Irbesartan, Isosorbide Mononitrate,  
Lansoprazole, Latanoprost, Levofloxacin, Levonorgestrel/Ethinyl  
Estradiol, Levothyroxine, Lisinopril, Lisinopril/HCTZ,  
Loratadine, Loratidine/Pseudoephedrine, Lorazepam, Losartan,  
Losartan/HCTZ, Lovastatin, Mateglinide, Mesalamine,  
Methylprednisolone, Metoprolol, Miglitol, Mometasone,  
Montelukast, Morphine, Mupirocin, Naproxen, Nisoldipine,  
Nitrofurantoin, Nizatidine, Ofloxacin, Olanzapine, Ondansetron,  
Oxaprozin, Oxycodone, Oxycodone/APAP, Paroxetine, Penicillin VK,  
Phenytoin, Potassium Chloride, Pramipexole, Pravastatin,  
Prednisone, Promethazine, Propoxyphene N/APAP, Propranolol,  
Quetiapine, Quinapril, Raloxifene, Ramipril, Ranitidine,  
Repaglinide, Risperidone, Rofecoxib, Salmeterol, Sertraline,  
Sildenafil, Simvastatin, Sotalol, Sumatriptan, Tamoxifen,  
Tamsulosin, Temazepam, Terazosin, Terbinafine,  
Tobramycin/Dexamethasone, Tolterodine, Tranylcypromine,  
Trazodone, Triamterine/HCTZ, Troglitazone, Valsartan,  
Venlafaxine, Warfarin, Zafirlukast, and Zolpidem.

Claim 44 (original): The composition according to claim 42  
wherein said pharmaceutical active is selected from the group  
consisting of abacavir, amprenavir, stavudine, zalcitabine,  
didanosine, delavirdine, efavirenz, hydroxyurea, indinavir,

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lamivudine, lopinavir, nelfinavir, nevirapine, ritonavir, saquinavir and zidovudine.

Claim 45 (original): The composition according to claim 42 wherein said pharmaceutical active is a cyclooxygenase inhibitor.

Claim 46 (original): The composition according to claim 45 wherein the cyclooxygenase inhibitor is COX-2.

Claim 47 (original): The composition according to claim 46 wherein the COX-2 cyclooxygenase inhibitor is celecoxib or rofecoxib.

Claim 48 (original): The composition according to claim 41 comprising a further step of applying a coating agent to the foam before the size reduction step (c).

Claim 49 (original): The composition according to claim 41 wherein the size reduced foam is molded into a shaped composite.

Claim 50 (original): The composition according to claim 49 wherein a coating agent is applied to the size reduced foam after it is molded into a shaped composite.

Claim 51 (original): The composition according to claim 50 wherein the shape of the shaped composite is selected from the group of shapes consisting of round, triangular, rectangular, polygonal, cylindrical, oval, oblong, capsule, tablet and caplet.

Claim 52 (original): The composition according to claim 41

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wherein the pharmaceutical or pharmaceutical active is in interstices between said microspheres.

Claim 53 (original): The composition according to claim 41 wherein the pharmaceutical or pharmaceutical active is non-covalently bound to said microspheres.

Claim 54 (original): The composition according to claim 41 wherein the pharmaceutical or pharmaceutical active is covalently bound to said microspheres.

Claim 55 (original): The composition according to claim 41 wherein the pharmaceutical or pharmaceutical active is contained within said microspheres.

Claim 56 (original): The composition according to claim 41 wherein the pharmaceutical is active or inactive metabolites of active pharmaceutical ingredients or salts of the metabolites of active pharmaceutical ingredients.

Claim 57 (original): The composition according to claim 41 wherein the pharmaceutical is a pro-drug which after oral administration generates active or inactive metabolites.

Claim 58 (previously amended): The composition according to claim 41 wherein the pharmaceutical is as a precursor which after oral administration generates active or inactive metabolites.

Claim 59 (previously amended): The composition according to

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claim 41 wherein the said pharmaceutical is prepared so as to become systemically available over a period of not less than two hours after administration to a human or other mammal.

Claim 60 (original): The composition according to claim 41 wherein said pharmaceutical composition is a time-release preparation.

Claim 61 (original): The composition according to claim 60 wherein said pharmaceutical elicits pharmacological or therapeutic activity.

Claim 62 (currently amended): A method of preparing a deformable syntactic foam for the delivery of a compound or chemical, the method comprising:

a) mixing together a carboxyvinyl polymer, a high molecular weight polysaccharide, silicic anhydride and a suitable microsphere to form a blended mixture having a LOD of from about 1% to about 10%; and

b) ~~reacting~~ mixing the mixture of a) with an organic solvent under conditions of high shear at temperatures of from about 10°C to about 25°C until a foam composition is formed wherein said foam composition is deformable ~~to the touch~~ and has a LOD of about 8% to about 20%.